Effectiveness of Diabetes Disease Management Programs for Reducing Health Care Utilization: a Systematic Review and Meta-Analysis

By

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Abstract

Background:

Diabetes Mellitus is a chronic disease associated with significant morbidity and healthcare costs. Although diabetes disease management programs have been shown to improve intermediate outcomes such as glycemic control, it is unclear whether these programs improve healthcare utilization outcomes.

Objective:

To conduct a systematic review and meta-analysis of randomized control trials (RCTs) to assess the effectiveness of disease management programs for reducing hospitalizations and emergency department (ED) visits in a population of adults with type II diabetes mellitus.

Methods:

I searched MEDLINE®, Embase, and Cumulative Index to Nursing and Allied Health Literature (CINAHL)® to find RCTs (published before January 1st, 2014) of disease management programs for adults with type II diabetes. Included trials had to measure either hospitalizations or ED visits. I extracted relevant data from each trial and graded the risk of bias of each included trial. I then performed a meta-analysis of those programs that reported similar measures of utilization rates.

Results:

Six RCTs met inclusion criteria. Four studies were conducted in the United States, one in Brazil, and one in South Korea. Educational and coaching components were the most common intervention components; care coordination and independent treatment adjustment by the case manager were less common. All six trials reported on ED utilization. Of these, three were able to be included in the meta-analysis to determine changes in ED utilization. Four studies

reported on hospitalizations; two of these were able to be included in the meta-analysis to determine changes in hospital utilization. A single study by Wu et al., showed borderline significance in its ability to reduce ED utilization with a risk ratio of 0.45 (95% confidence interval 0.21-0.98). However this statistically significant outcome was only present with an intention-to-treat analysis and was not present in the authors own as-treated analysis. No other study, or pooled meta-analysis found a significant difference between disease management programs and usual care for reducing health care utilization.

Conclusion:

Disease management programs show no benefit over usual care for reducing ED visits or hospitalizations. Overall, I found few studies that met inclusion criteria. Future trials may help determine whether diabetes disease management programs affect healthcare utilization rates.

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Introduction

Background of Diabetes Mellitus

Diabetes Mellitus is a chronic disease associated with significant morbidity and healthcare costs. As of 2014, the Center for Disease Control and Prevention (CDC) estimated that nearly 29.1 million people in the United States (U.S.) suffer from diabetes. Furthermore, the prevalence of diabetes among adults in the U.S. was 9.3% in 2014, up from about 3.5% in 1980 (1–3). The CDC estimates that the prevalence of diabetes could increase up to 1 in 3 adults by 2050(4). The majority of this growth has been in patients with type II (or non-insulin dependent) diabetes. This is supported by an increasing and correlated prevalence of pre-diabetes, a partially insulin resistant condition, which is a known precursor to type II diabetes(2,3). The CDC estimates that 90%-95% of diabetes in the U.S. is type II diabetes. Increasing levels of obesity in the U.S. population is thought to contribute to the increased prevalence of type II diabetes; both obesity and type II diabetes are caused (in part) by low levels of physical activity and poor diet(1,2).

Diabetes mellitus, hereafter referred to simply as diabetes, is associated with several adverse health outcomes, such as chronic kidney disease (CKD), microvascular complications, (e.g., diabetic retinopathy) macrovascular complications (e.g., cardiovascular disease [CVD]), and others. Microvascular complications are known to result as a direct consequence of chronic hyperglycemia(5,6). Macrovascular complications have so far been shown to be non-causally associated with chronic hyperglycemia(7). A clear epidemiological association is present between worsening chronic hyperglycemia and increased risk of CVD endpoints, such as myocardial infarction (MI). This evidence is a result of several well-powered, non-randomized prospective cohort studies(8–10). Randomized trials have suggested trends towards reduction in CVD endpoints, such as MI, as a result of direct improvement in hyperglycemia. However, the results have been non-statistically significant(5,6).

Diabetes incurs significant financial strain to both the healthcare system, and to patients. The CDC estimates that as of 2014, the costs related to diabetes care in the U.S. reached $176 billion in direct medical costs and $69 billion in indirect medical costs(2). This is up from 2007 where direct and indirect medical costs for diabetes costs were estimated to account for $153 billion and $65 billion, respectively(11). Direct medical costs account for money directly attributable to medical care, such as provider, hospital, and medication costs. Indirect costs include such aspects as lost productivity. As of 2014, the CDC estimates that a person with diabetes uses 2.3 times more medical services, than a person without diabetes(2).

Following the evidence that improvement in blood glucose levels reduces diabetic complication rates, pharmacologic management of hyperglycemia has become a mainstay of diabetes care. Foundational studies in this area have been the Diabetes Complications and Control Trial, the United Kingdom (UK) Prospective Diabetes Study, and a study by Ohkubo et al. on intensive insulin regimens for prevention of microvascular complications(5,6,12). The Diabetes Complications and Control Trial demonstrated that in the treatment of type I (or, insulin dependent) diabetes, intensive therapies that maintained blood glucose near normal physiologic levels reduced diabetic complications, such as kidney disease, retinopathy, and neuropathy(5). Yasuo Ohkubo and colleagues applied this same principle to individuals with type II diabetes by demonstrating a reduction in microvascular complications as a consequence of intensive insulin regimens in this population(12). Finally, the UK Prospective Diabetes Study showed that in individuals newly diagnosed with type II diabetes, a similar improvement in blood glucose levels precipitated a similar decrease in diabetic complications, regardless of whether an insulin or an oral hypoglycemic regimen were used as therapy(6).

History of Disease Management Programs

Despite the wealth of evidence related to best practice in clinical diabetes care, the prevalence of diabetes continues to increase, as to associated costs of medical treatments, both in the U.S. and abroad(1,13,14). Many feel that traditional clinical interventions that often focus on pharmacologic therapy alone have been insufficient in addressing diabetes(15). Diabetes is a chronic condition that requires regular self-care with frequent blood glucose monitoring, and often frequent clinical monitoring and adjustment of chronic pharmacological therapy. In addition, multifactorial interventions to improve patient adherence are essential for prevention of diabetes related complications. For example, interventions that focus on maintaining a healthy body mass index, receiving regular disease specific screenings, and maintaining a healthful diet are felt to be important in the overall care of patients with diabetes (16). In response to this complex set of recommendations, the Community Preventative Service Task Force (Task Force), in 2002, recommended the use of disease management and case management services in order to improve outcomes related to diabetes care(15). The Task Force defined disease management as an "Organized, proactive, population-based, and integrated" set of interventions that focused on the following: 1) the structure, processes, and resources of a health care delivery system; 2) provider knowledge, attitudes and behavior towards screening and treatment; and 3) patient knowledge, self care behaviors, and psychological mediators(15).

The Disease Management Association of America (DMAA) has offered an alternative definition of disease management. They state that a disease management program "supports the physician or practitioner/patient relationship and plan of care; emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies; and evaluates clinical, humanistic, and economic outcomes on an on-going basis with the goal of improving overall health (pg. 116)"(17).

In both cases, these definitions share a focus on population-health, an emphasis on evidence-based interventions, and a purpose to complement, rather than supplement, the traditional provider/patient interaction.

Efficacy of Diabetes Disease Management Programs for Glycemic Control

Following recommendations of the Task Force, a number of randomized control trials (RCTs) have provided evidence as to the efficacy of disease management programs for lowering hemoglobin A1c (HbA1c) in diabetic populations. Compared to usual care, they have led to better glycemic control for patients with diabetes. However, the absolute effects on HbA1cs have been modest. A meta-analysis including 41 of these studies that compared disease management programs with standard care found an average decrease in HbA1c of 0.38% (95% CI 0.29% to 0.47%), favoring the disease management interventions (17). This review, along with another systematic review, found that disease management programs showed greater effectiveness if they included the following: 1) community educators 2) expanded scope care providers, such as pharmacists and nurses that could independently adjust treatments 3) incorporated treatment algorithms, and 4) provided more frequent contact with patients(17,18). In particular, the systematic review by Pimogouguet et al. showed that using expanded scope care providers in a disease management program led to an absolute HbA1c decrease in 0.6% versus a decrease of 0.28% in those programs that did not use expanded scope care providers ($p<0.001$)(17). Likewise this review also found that programs which contacted patients several times per month had greater efficacy than programs which contacted patients less than one time per month; an absolute decrease in HbA1c of 0.56% versus 0.3%, respectively ($p=0.033$).

Efficacy of Diabetes Disease Management Programs on Healthcare Utilization

While the effect of diabetes disease management programs on intermediate and clinical outcomes is well characterized, it is unclear whether diabetes disease management programs

improve healthcare utilization outcomes such as rates of hospitalization and emergency department (ED) visits. The question of reduced utilization, specifically, has become even more relevant as the Patient Protection and Affordable Care Act (ACA) has generated renewed interest in managed care. New provisions in the ACA allow for the creation of Accountable Care Organizations (ACOs). These new care structures will allow health systems to share in cost-savings generated by better provision of care, but conversely will require them to begin accepting some of the financial risk of the populations they care for(19,20). This financial impetus will likely spur health systems to further explore and invest in novel care structures, such as disease management programs, in the hopes of generating cost saving interventions for complex patients. One potential mechanism of cost-savings comes from the shifting of costs from expensive inpatient services, to less expensive outpatient services.

The literature regarding the ability of diabetes disease management programs to reduce hospitalizations and ED visits is limited. Several non-randomized prospective trials and retrospective studies have examined this topic(21–26). All of the prospective studies were able to observe a reduction in hospitalization or ED visits for patients enrolled in diabetes disease management programs. These results ranged from relative reductions of 18% to 51%(23,25,26). However, the prospective studies were all based on a pre-intervention, post-intervention study design, with no control group. Even when performed well, pre-post intervention study designs are influenced by the Hawthorne effect and regression towards the mean, which confound the true results of the study. Regression towards the mean, in particular, is thought to play a significant role in influencing disease management studies(27,28). This is due to the fact that disease management programs are often targeted towards the sickest patients with the highest levels of health care utilization. Because disease management programs target these outliers, some portion of the patients they treat will likely get better on their own, regardless of what intervention they receive(27).

In the case of the studies that used a retrospective cohort design, several used propensity score matching techniques in order to select a relevant control population. The effect size from these studies was more limited and ranged from no difference to a reduction in hospitalizations of 17.5%(21,22,24). The propensity score matching technique is one way that has been advocated for retrospective studies to select a relevant control population with similar characteristics and thus compensate for selection bias and natural regression towards the mean(27).

Finally, not all of the evidence regarding disease management programs has been favorable. A recent study by McCall and Cromwell likely represents the largest randomized control trial of disease management programs to date(28). This study reported on the Centers for Medicare and Medicaid Services (CMS), Medicare Health Support Pilot Program. This pilot program was a 36-month long, randomized trial involving 15 commercial disease management programs and measured their ability to improve process measures, reduce health care utilization, while maintaining cost neutrality. The programs targeted a total of 242,417 Medicare patients who had either diabetes mellitus or heart failure and who had medical costs 35% above average. About half of the participants had diabetes, while the other half had either heart failure alone or heart failure and diabetes concurrently. In aggregate, the trial reported no difference in hospital admissions or ED utilization between the disease management group and usual care. In addition, only 14 of the 40 process measures showed consistent and statistically meaningful improvement in favor of disease management. Finally, none of the disease management programs studied were able to maintain cost neutrality; the disease management intervention as a whole was significantly more expensive than usual care(28).

It should be noted that all of these programs were commercial programs that were poorly integrated with the patients' care teams. Likewise, this trial targeted both patients with diabetes and patients with heart failure, rather than patients with only diabetes. There may be important differences in costs and frequency of utilization among these patients. Finally, the study noted that all the disease management programs struggled to recruit "ideal patients". Their interpretation of this difficulty was that the patients who were randomized were, in general, healthier than what might be considered "ideal" for a disease management intervention. The authors suggest that this healthier population may not have benefited as much from the intervention than would a population with greater disease severity, thus potentially reducing the effect size(28,29). All of these issues limit the applicability of this study's results. However, this study does challenge the assumption that disease management programs lead to reductions in healthcare utilization and cost, and suggests that a closer and more critical look at the literature surrounding diabetes disease management programs is needed.

To address this issue, I conducted a systematic review and meta-analysis on the effect of disease management programs in reducing hospitalizations and ED visits. To my knowledge, no prior study has synthesized this evidence.

Methods

Defining Disease Management

So far there has been no clear consensus on what constitutes a disease management program. This is likely due to the different possible intervention components that can characterize disease management programs. Additionally, disease management programs may overlap with other non-disease management interventions that aim to improve healthcare delivery. Therefore, in order to develop my inclusion and exclusion criteria, I considered several definitions or conceptualizations of "disease management". I was motivated by a need to determine a

definition of disease management that would both be broad enough to allow for differences between programs, but also a definition that was concrete enough to discern between disease management programs and other changes to health care delivery.

The definitions previously offered by the DMAA and Task Force both allow for differences in interventions between disease management programs, but also emphasize a set of core principles of all disease management programs. Specifically, that they are evidence based, population health focused, and complementary to clinical care. However, although they useful in identifying possible disease management programs, I felt that neither definition was discriminatory enough to discern between disease management programs and other health services interventions for the purpose of this literature review.

As part of their systematic review of disease management programs to improve blood glucose control, Pimouguet et al. (2011) created a more specific working definition of disease management programs with the goal of identifying specific components that could make up such a program. The authors defined disease management as an "ongoing and proactive follow-up of patients that includes at least two of the following five components: patient education (dietary and exercise counseling, self-monitoring, and knowledge of disease and medication); coaching (the disease manager encourages the patient to overcome psychological or social barriers that impede autonomy or improvement in medication compliance); treatment adjustment (the disease manager is able to start or modify treatment with or without prior approval from the primary care physician); monitoring (the disease manager gets medical data from the patient); and care coordination (the disease manager reminds the patient about upcoming appointments or important aspects of self-care and informs the primary care physician about complications, treatment adjustment or therapeutic recommendations)."(17).

I chose this definition to inform my inclusion and exclusion of trials as it relies on a combination of factors when defining a program and appeared to be a good fit for the diabetes care management literature. It allows for flexibility of intervention components within a single program. And, although the definition allows for flexibility, it is also built upon a relatively discrete and well-characterized set of components allowing for the inclusion of similar interventions during abstract and full-text review.

Search Criteria

With the help of a health-sciences librarian, I conducted a literature search using MEDLINE®, Embase, and Cumulative Index to Nursing and Allied Health Literature (CINAHL)® for relevant English-language studies published prior to Jan 1st 2014. My search terms included: "Diabetes Mellitus, Type 2", "Preventive Health Services", "Patient Care Management", "Case management" "Health Education", "Counseling", "Emergency Department", "Emergency health service", "Emergency ward", "Emergency Room", "Hospitalization", and "Hospitals/Utilization (MeSH term)". The full search criteria are presented in **Appendix 1**.

Study Selection and Inclusion and Exclusion Criteria

Table 1 outlines inclusion and exclusion criteria. Briefly, I included RCTs of interventions that fit the definition of disease management described by Pimouguet et al.(17). I specifically excluded transitional care interventions given that the scope and goals of these programs are often different from longitudinal outpatient disease management programs. I defined transitional care programs to be time-limited interventions specifically aimed at increasing coordination of care for patients newly discharged from the hospital , avoidance of readmission, or both. Of note, I specifically did not exclude trials from other countries, as I felt that major principles regarding coordination of care for individuals with chronic diseases would be broadly applicable, regardless of country of origin. I also chose to focus on type II diabetes

as it accounts for a large proportion of the global diabetes burden, especially in the elderly, comorbid population that is likely to receive disease management services.

Study titles and abstracts were reviewed for relevance against the inclusion/ exclusion criteria. I then reviewed the full text of those articles that either fit inclusion criteria based on the abstract or if it was unclear whether the study should be included or excluded from the analysis.

Data Abstraction and Quality Assessment

Studies that met inclusion criteria at full text review were included in data abstraction. For each study, I recorded in an outcomes table the following information: study identifiers, study design features, population characteristics, description of the intervention and comparator, baseline population health care utilization, and health utilization outcomes. If studies reported on multiple time points for health care utilization, only the cumulative outcome for the entire study period was abstracted.

I assessed the internal validity (or quality) of each included trial using a predefined set of criteria that assessed the following: selection bias, performance bias, detection bias, attrition bias, reporting bias, and possible confounding. These criteria were based on the process of the U.S. Preventive Services Task Force and the National Health Service Centre for Reviews and Dissemination (United Kingdom)(30,31). From these criteria, I then rated each study in terms of overall risk of bias: low, medium, and high. All studies, regardless of risk of bias were included in the review.

Meta-Analysis of Utilization Outcomes

In order to increase comparability of outcome measures, I used information provided by the studies to calculate relevant measures of association. For example, when possible and where

count data for health care utilization (i.e., number of hospitalizations and ED visits) as well total person-time was given or could be estimated, I calculated incidence rate ratios (IRR). Where the proportion of individuals admitted was given, I attempted to calculate risk ratios (RR), and if this was not possible I estimated an odds ratio (EOR). In all cases I calculated utilization measures using an intention to treat framework. This meant that outcome measures, and subsequent measures of association were calculated using the reported group sizes immediately after randomization, rather than on an as-treated basis. In all cases an association measure less than 1 favors disease management for reducing health care utilization and an association measure greater than 1 favors usual care for reducing health care utilization.

Because disease management programs are heterogeneous by nature of the multiple interventions they can include, I used a random effects model when I calculated a pooled effect size. I included in the same model, studies that had similar reported, or calculated measures of association. In all cases, a p value of 0.05 or less was considered to be statistically significant, with 95% confidence intervals (CI) given for association measures. I used both a chi-squared statistic and an I^2 statistic to assess for differences in the studies that resulted from statistical heterogeneity(32). All analyses were conducted using the "metafor" package for R 3.0.2(33,34).

Results

Literature search and screening

512 original articles were identified from all database searches. Of these, 6 articles met the inclusion criteria for this review. The process of study selection is summarized in **Figure 1**.

Characteristics of Study Populations

All six included RCTs evaluated a disease management program compared to usual care. The mean age for the study populations was 60 years old with a range of 51 to 69 years. The racial/

ethnic distribution of subjects within each study was relatively homogeneous, but the racial/ ethnic distribution of subjects between studies was remarkably heterogeneous. Two studies, Wu et al. conducted in Taiwan(35) and Borges et al. conducted in Brazil(36), did not report racial/ ethnic distribution. Two other studies from the U.S., Gary et al. and Babamoto et al. included only African Americans and Hispanics, respectively(37,38). The other two studies conducted in the U.S., from Aubert et al. and Taveira et al. had no racial/ ethnic inclusion criteria and enrolled mainly Caucasians, 73% and 99%, respectively(39,40). With one exception, the studies recruited a majority of women. The exception, a trial by Taveira et al., was conducted through the Veterans Administration and recruited only 2% women. The remaining five studies had an average demographic composition of women of 66% with a range of 60% to 73.5%(35,36,38–40).

Five of the six studies included only people with type II diabetics. The study by Aubert et al. included primarily type II diabetics, but type I diabetics accounted for 17% and 8% of the intervention and control cohorts, respectively(39). Five of the six studies reported the average glycemic control of their population at enrollment, measured via HbA1c; the average HbA1c was 8.5% with a range of 7.7% to 9.5%. In all cases, HbA1c was similar between intervention and control groups. Duration of diabetes diagnosis also varied within and between studies. Babamoto et al. specifically included only patients diagnosed with diabetes in the last six months(38). Three of the remaining five studies included information regarding duration of diabetes diagnosis for their cohorts. The average duration of diabetes was 8.8 years. In all three cases, this duration was similar between intervention and control cohorts.

Studies varied in other inclusion and exclusion criteria as well. Most of the trials had an inclusion age of 18 years old. Two of the studies required participants to be 30 years or older or 25 years or older(35,37). Five of the studies excluded participants for additional reasons: 1)

pregnancy or gestational diabetes(38–40), 2) medical or psychiatric conditions that would interfere with self care(35,39,40), 3) other complications (hepatocellular carcinoma, infected with human immunodeficiency virus [HIV])(36), 4) Blood glucose control (exclusion of HbA1c under 7%, or inclusion only if over 6.5%)(39,40).

Intervention Description

All of the included trials used either a pharmacist or a nurse case manager to deliver the intervention. Two of the six studies also had an intervention with a trained layperson that worked as a community health worker. Gary et al. provided the community health worker intervention concurrently with case manager services(37). Babamoto et al. provided the community health worker as an alternate treatment arm and was unique in having three study arms, one arm that received only the community health worker intervention, one arm that received only a case manager, and a usual care arm(38). Four of the six interventions enabled the case manager to independently adjust pharmacologic treatment, based on a pre-determined treatment algorithm(36,39,40).

Three of the six studies used an initial in-person interaction along with follow-up either via telephone or a mix of telephone or in-person follow-up(35,37–39). Two of the six studies used only in-person interactions between the disease manager and patient(36,40). Five of the six studies had interactions between the disease management program and the patient at least once a month. Gary et al. reported the least frequent interactions, with interactions at least three times per year for the community health worker and at least once per year for the nurse case manager. This led to a minimum of four patient interactions per year, with more frequent interactions if necessary(37). All the studies varied significantly as to which of the five aspects of a disease management program, (outlined in the methods section above), were included in the intervention. All six studies included an educational component to their programs, four

included coaching components and another four included active monitoring of their participants. The least likely components to be used in the disease management programs were care coordination and treatment adjustment, with only two and three studies reporting use of these components, respectively.

In all six of the studies, the comparison group was described as receiving, "usual", or "standard care", with a physician provider. Three studies specifically described interventions (in addition to provider visits) that were part of standard care. In the study by Wu et al., patients who were newly diagnosed with diabetes received 15 minutes with a nurse educator and a nutritionist(35). In the study by Taveira et al. all patients with diabetes received two hours of diabetes education every week, for four weeks, followed by monthly education sessions(40). Patients receiving standard care in the study by Gary et al. received automated screening reminders every six months(37).

Description of Reported Outcomes

Four studies measured health care utilization as a primary or secondary outcome. The other two studies measured utilization as a "harm"; neither of these studies described how utilization outcomes were collected(39,40). All six of the studies measured and reported on frequency ED visits. Only four out of six studies also reported on rates of hospitalizations. In the majority of the cases, five out of six studies, all cause hospitalization and ED usage was measured. The study by Wu et al. chose to measure ED visits and hospitalizations that were related to diabetes only, and did not provide a measure of "all-cause" utilization (35). Five of the six studies reported on the proportion of participants who were hospitalized or visited the ED. The only exception was the trial conducted by Gary et al., which reported the total number of visits to the ED, and total number of hospitalizations.

Studies varied in how utilization rates were ascertained. In two studies it was unclear how utilization rates were measured(39,40), two studies used self report(35,38), Borges and colleagues expressly used claims data(36). And Gary et al. used a combination of patient medical records and inquires into local hospitals in order to determine utilization rates(37).

Studies varied in the length of outcomes that were collected. Three studies had follow-up times of six months(35,38,40). Two studies had follow-up times of one year(36,39). Tiffany Gary and colleagues followed subjects out to 36 months(37).

Description of Setting:

As stated above, four of the six studies were conducted in the U.S. The study conducted by Wu et al. took place in Taiwan and the study by Borges et al. took place in Brazil. In all cases the interventions were conducted in an outpatient setting. Borges et al. recruited subjects who were patients of an endocrinology clinic(36). The remaining studies recruited subjects from the surrounding area or subjects who were patients of the health system affiliated with the study. A table summarizing these interventions is given in **Table 2** and a more complete summary of disease management criteria that were fulfilled by each intervention is given in **Appendix 2**.

Description of Quality

I rated one trial as having low risk of bias(37). Four were rated as medium risk of bias(35,36,39,40). The Babamoto et al. trial was rated high risk for bias both due to high attrition as well as high risk of measurement bias. The authors relied on self-report data alone to determine utilization rates. The most common methodological problem encountered was high rates of attrition. Another common methodological problem was measurement bias (e.g., one method, such as self-report only to determine utilization outcomes). A more complete description of quality determination is given in **Appendix 3**.

Emergency Department Utilization

Three studies reported outcomes related to ED visits in a way that allowed pooling of data in a meta-analysis to determine a pooled risk ratio (**Figure 2**). Because the Babamoto et al. study included two study arms, each arm was treated as a separate data point in the meta-analysis. Although the pooled estimate favored disease management programs versus standard care in the reduction of ED visits, this result was not statistically significant, (RR 0.78; 95% C.I. 0.53-1.15), the statistical heterogeneity of these studies in the random effects model was low, I^2 = 3.6%(38–40).

The remaining three studies allowed for the calculation of three different association measures. Wu et al. reported only diabetes related ED visits and found no difference between the two groups, (RR 0.63; 95% CI 0.35 – 1.15)(35). Using the information provided by Borges et al. I was able to calculate an estimated association measure, (EOR 0.70; 95% CI 0.30 – 1.64)(36). Finally, Gary et al. also reported a non-significant decrease in the number of ED visits, (IRR 0.84; 95% CI 0.61 – 1.15)(37). In five of the six trials, the measure of association showed a trend towards reduced ED visits in favor of the disease management intervention, but none of these differences were statistically significant. A summary of reported ED visits and their related association measures are given in **Table 3**.

Hospital Utilization

I included the last two studies, from Aubert et al. and Taveira et al., in a meta-analysis of the effect of disease management programs for the reduction of all-cause hospitalization(39,40). This meta-analysis is given in **Figure 3**. The pooled estimate slightly favored disease management programs for reducing hospitalizations for patients with diabetes, when compared

to standard care. However, the pooled result was not statistically significant (RR 0.91; 95% CI 0.39 to 2.13). Again the heterogeneity measure between these two studies was low, $I^2 = 0$.

Four studies reported on hospital utilization rate. Again, Wu et al. reported on only diabetes related hospitalizations. Of note, this group reported no significant difference in hospitalizations. However, in my intention-to-treat analysis, the reduction in hospitalizations favoring disease management obtained statistical significance, (RR 0.45; 95% CI 0.21-0.98). Wu et al. performed their analysis on individuals who completed the program with no mention of how missing data was handled. Gary et al. again reported a non-significant decrease in the number of hospitalizations, (IRR 0.83; 95% CI 0.64-1.07). A summary of reported hospitalization rates and their related association measures are given in **Table 4**.

Discussion:

Across the six included trials in this review, diabetes management programs appear to offer no additional benefit above usual care in reducing health care utilization rates. No single study or meta-analyses of the included trials found a statistically significant reduction in health care utilization. The significant heterogeneity in terms of how outcomes were reported limited my ability to pool results. Effect sizes for reductions in ED usage varied considerably from a relative risk reduction of 76%, to a level of equal efficacy, when compared to standard care. The variability in effect size regarding reduction of hospitalizations was less, but still considerable, from a 55% to a level of equal efficacy. Taken in aggregate, these results suggest that disease management programs for diabetic patients perform no better than usual care in their ability to prevent ED visits and hospitalizations.

These results are consistent with other studies and reviews of disease management programs that have found lackluster results in regards to the efficacy of disease management programs.

Most notably, the results of this review are in accordance the Task Force's findings(15). In the review conducted by the Task Force, their results were suggestive of a reduction in health utilization, but in the end they were unable to show a statistical difference between disease management and usual care for any of the identified studies. The pooled meta-analysis of disease management studies, presented here, suggests a trend towards decreased utilization; 33% for ED visits, and 9% for hospitalizations that was not statistically significant (37,38,40).

Since few trials met inclusion criteria, we were not able to assess whether these programs are more or less efficacious for certain subgroups of patients. Likewise, the limited number of studies and the variability in their incorporation of the five components of disease management programs laid out by Pimouguet et al., meant that I was not able to assess whether the different possible components of disease management programs were more or less effective than one another. My review did show, however, that educational components were the most common intervention incorporated, with all six studies incorporating some educational aspect to their program. Conversely, care coordination and treatment adjustment components were the least common interventions used **(Appendix 2).** This may reflect an easier ability to implement educational components to a program, or may alternatively reflect a perception that patient self-care education is an important aspect of all diabetes care(16).

Limitations of this Systematic Review and Meta-Analysis

Due to limitations in time and resources, I was not able to perform a hand search of the citation lists provided in other studies or hand search systematic reviews on the topic of disease management for diabetes. A manual search of relevant disease management studies may have allowed me to identify additional disease management trials that reported on health care utilization. Similarly, a search of grey literature was not performed. This may have identified

unpublished studies or unpublished utilization outcomes from other trials that could provide an assessment of publication bias in this literature base.

Additionally, this study was limited to RCTs. Non-randomized trials have been advocated as one way to expand the body of knowledge regarding health services research(27,29). Therefore, the body of evidence regarding disease management programs would have been larger had non-randomized prospective studies and retrospective studies been included. However, because of the significant heterogeneity that already exists amongst types of disease management programs, I attempted to limit other aspects of the review in order to promote comparability. Future reviews may be able to successfully incorporate these other study designs as a way of broadening the knowledge base.

Limitations in the Literature

A major limitation of this literature was the small number of studies identified related to this topic. As discussed above, there may be a potential for publication bias or outcome reporting bias related to this literature and this could be assessed in future work. For the trials that were identified, there was significant heterogeneity in how authors measured and reported health care utilization outcomes. This greatly limited my ability to meaningfully pool the outcomes in order to create an aggregate estimate of effect size. As noted above, many of the studies did not have a primary goal of measuring health care utilization. In those studies, therefore, the reliability of the measures may be in question and this therefore limits the conclusions that can be drawn. Finally, many of the studies reviewed contained less than 100 subjects in each arm and measured only a handful of healthcare utilization events. These small numbers of utilization events limits the ability to draw statistically meaningful conclusions from the studies.

Future Directions For Research

This review may add the most towards recognition of the scarcity of evidence that still exists regarding the ability of diabetes disease management programs to improve health care utilization outcomes. As part of addressing this issue, future studies will need to focus on two aspects of study design: increased statistical power (e.g., larger sample sizes), and determination of utilization outcomes through multiple, valid measures.

Additional well-designed studies will allow two important questions to be addressed. This first is whether diabetes disease management programs are effective for reducing health care utilization in certain sub-groups of diabetic patients. Theoretically, patients who are sicker will stand to benefit more from the services offered by disease management programs. The systematic and improper selection of patients who are "too healthy", has been one justification for the poor performance of past disease management programs(28,29). Future studies may show whether the selection of a source population that has poorer health metrics improves the effectiveness of disease management programs. Additionally, the majority of the trials included here lasted less than one year, this is significantly shorter than the time it takes for most diabetic complications to develop. Future studies should also therefore consider lengthening the study period to help assess effectiveness of disease management programs. The second question is whether certain components of disease management programs prove to be effective at reducing health utilization. In this regard, investigators may do well to replicate the components of diabetes disease management programs that have been most effective for improving intermediate outcomes (e.g. HbA1c). Future studies should therefore seek to provide patients with frequent contact with case managers that are able to independently adjust patient treatment regimens. Likewise they should rely less heavily on patient education components(17,18), which perhaps are easier to implement, but have shown little efficacy in improving intermediate outcomes.

It is likely that in response to increasing costs related to the treatment and morbidity of diabetes, health systems will continue to restructure their diabetes care by incorporating interventions such as disease management programs. A better understanding of how these programs affect health care utilization is needed in order to ensure the resources are allocated in a way that benefits the patient. In summary, while this review has shown no difference in the ability of diabetes disease management programs to reduce health care utilization when compared to usual diabetes care, it has highlighted the significant gaps in knowledge that still exist in regards to these programs and offers possible solutions for rectifying those gaps.

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Table 1 - Inclusion and Exclusion Criteria		
Study Aspect	**Inclusion Criteria**	**Exclusion criteria**
Language	Full text is in English	Full text is in another language
Population	Adults with type II diabetes (Included if the majority of subjects had type II diabetes)	Majority of subjects had type I diabetes.
Intervention	Designated disease manager who has longitudinal relationship with patient and provides 2 of the following: patient education, coaching, treatment adjustment, monitoring, or care coordination. Disease manager can be an allied health professional (e.g. pharmacist, nurse, etc.) or trained layperson. Intervention is targeted towards diabetes care.	Intervention addresses only one or none of these components (e.g., education only interventions). Transitional care programs (e.g., time limited and focused on populations transitioning from hospital to home). Intervention is primarily targeted towards another chronic disease (e.g., heart failure).
Comparison	Standard care for diabetic patients	Comparative effectiveness trials (e.g., studies comparing one type of intervention with another).
Outcome	Emergency department (ED) visits or hospitalizations.	Healthcare costs, risk prediction tools, intermediate outcomes (e.g., HbA1c), mortality.
Study Design	RCTs	All other study designs (e.g., non-randomized trials, cohort studies, case-control studies, epidemiological studies)

Figure 1 – Disposition of Articles

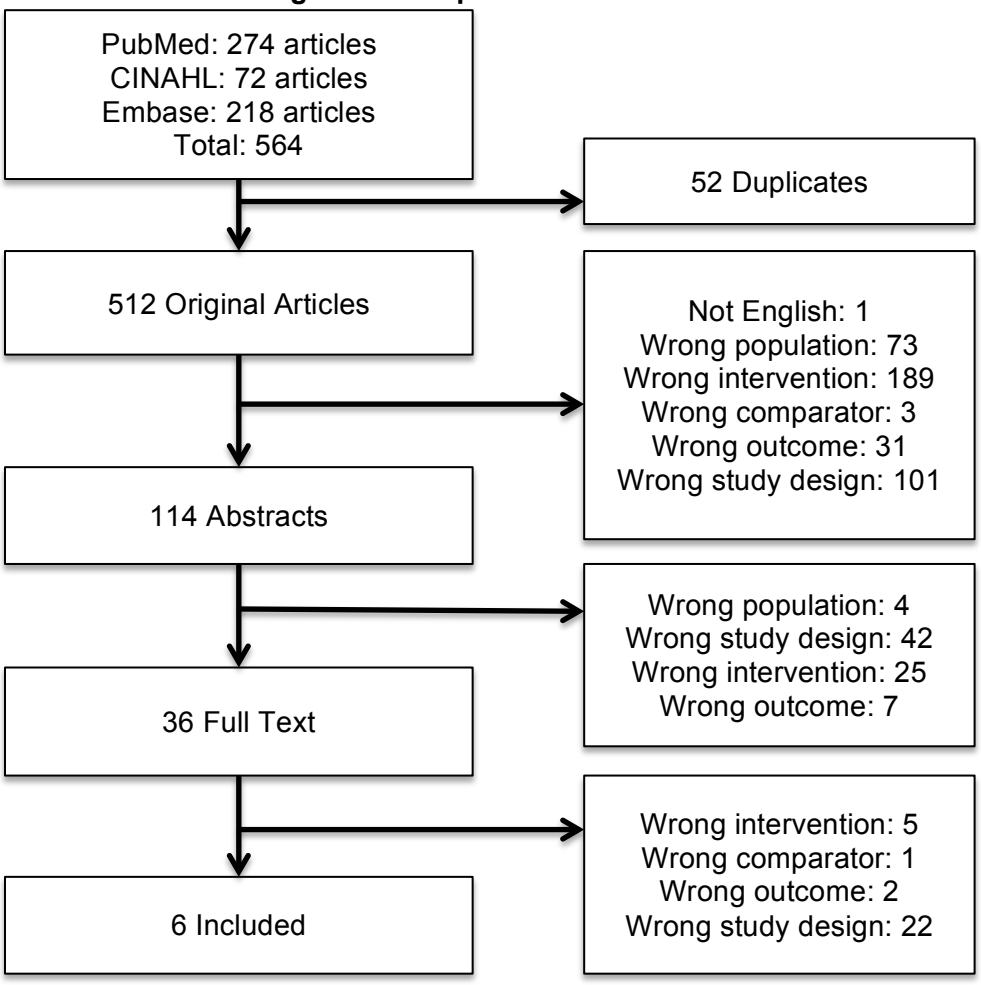


Table 2 - Description of Interventions			
Author, year/ Outcome Timing (months)	**Outcome Measure**	**Intervention / Sample Size (N)**	**Intervention description**
Wu, 2011 (6)	Rate of diabetes related ED visits and hospitalizations	Control (77)	Standard care plus 10-15 minutes of education by nurse educators and 10-15 minutes by a nutritionist.
		Intervention (81)	Standard care plus - 4 weekly group education sessions led by a nurse case manager. Follow-up call by nurse 8-16 weeks after initiation of program.
Aubert, 1998 (12)	Rate of all cause hospitalizations and ED visits	Control (67)	Standard care
		Intervention (71)	Standard care plus – Initial visit with the nurse case manager with follow-up 2 weeks later. Case manager could independently alter the treatment algorithm. Also provided guidance for meal planning and exercise. The nurse care manager had weekly follow up calls if the patient used insulin. The nurse care manager called every other week if they were using an oral hypoglycemic. Patients also received a 5 week educational program with quarterly follow-up.
Gary, 2009 (36)	Rate all cause hospitalizations and ED visits	Control (273)	Standard care plus 6 month automatic reminder calls about screening.
		Intervention (269)	Standard care plus - Community health workers focused on nutrition, physical activity, medication adherence, appointment adherence, foot care, and socioeconomic issues. Patient had at least 3 visits per year with the community health worker. Nurse case managers provided clinical education related to such things as medication usage. Patient received at least 1 visit per year with the nurse case manager.

Table 2 - Continued			
Author, year/ Outcome Timing (months)	**Outcome Measure**	**Intervention / Sample Size (N)**	**Intervention description**
Taviera, 2011 (6)	Rate all cause hospitalizations and ED visits	Control (44)	Standard care plus - 4 weekly 2-hour diabetes education sessions, followed by monthly 2-hour diabetes education sessions. Education session were led by pharmacists, nutritionists, and nurses
		Intervention (44)	Standard care plus - 4 weekly sessions for 2 hours. Then 5 monthly education sessions also for 2 hours. First hour of session was spent on education topic led by pharmacist, nutritionist or nurse. In the second hour the clinical pharmacist titrated meds based on a home diary
Borges, 2011 (12)	Rate of all cause ED visits	Control (31)	Standard Care
		Intervention (40)	Standard care plus - A monthly visit to pharmacist who followed clinical and admission data, they provided dietary and pharmacological education. They also provided treatment adjustment based on algorithm.
Babamoto, 2009 (6)	Proportion of patients who visited the ED for all causes	Control (108)	Standard care
		Community Health Worker (104)	Standard care plus - A community health worker; a trained layperson from the community. Intervention had a 10 week 1-on-1 educational component, followed by telephone calls to reinforce education and help tackle barriers. Average of 11 follow-up visits per 6-month period.
		Case Manager (105)	Standard care plus - case manager; a registered nurse who monitored clinical outcomes as well as educational outcomes, helped to incorporate provider treatment plan and refer to community resources. Average of 1 contact per month.

Table 3 – ED Utilization

Author, year	Risk of Bias (overall)	Outcome Timing (in months)	Study Arm (N)	Reported End of study ED counts	Association Measure of ED visits (95% Confidence Interval) / Association Measure Type
Wu, 2011	Medium	6	Control (77)	21	
			Intervention (81)	14	0.63 (0.35-1.15) / RR
Aubert, 1998	Medium	12	Control (67)	4	
			Intervention (71)	1	0.24 (0.03-2.06) / RR
Gary, 2009	Low	36	Control (273)	811	
			Intervention (269)	665	0.84 (0.61-1.15) / IRR
Taviera, 2011	Medium	6	Control (44)	17	
			Intervention (44)	17	1.00 (0.60-1.68) / RR
Borges, 2011	Medium	12	Control (31)	Average 0.8 (SD 0.7)	
			Intervention (40)	Average 0.6 (SD 1.2)	0.70 (0.30-1.64) / EOR
Babamoto, 2009	High	6	Control (108)	15	
			Community Health Worker (104)	7	0.49 (0.21-1.14) / RR
			Case Manager (105)	12	0.82 (0.40-1.67) / RR

Figure 2 – ED Visit Meta-Analysis

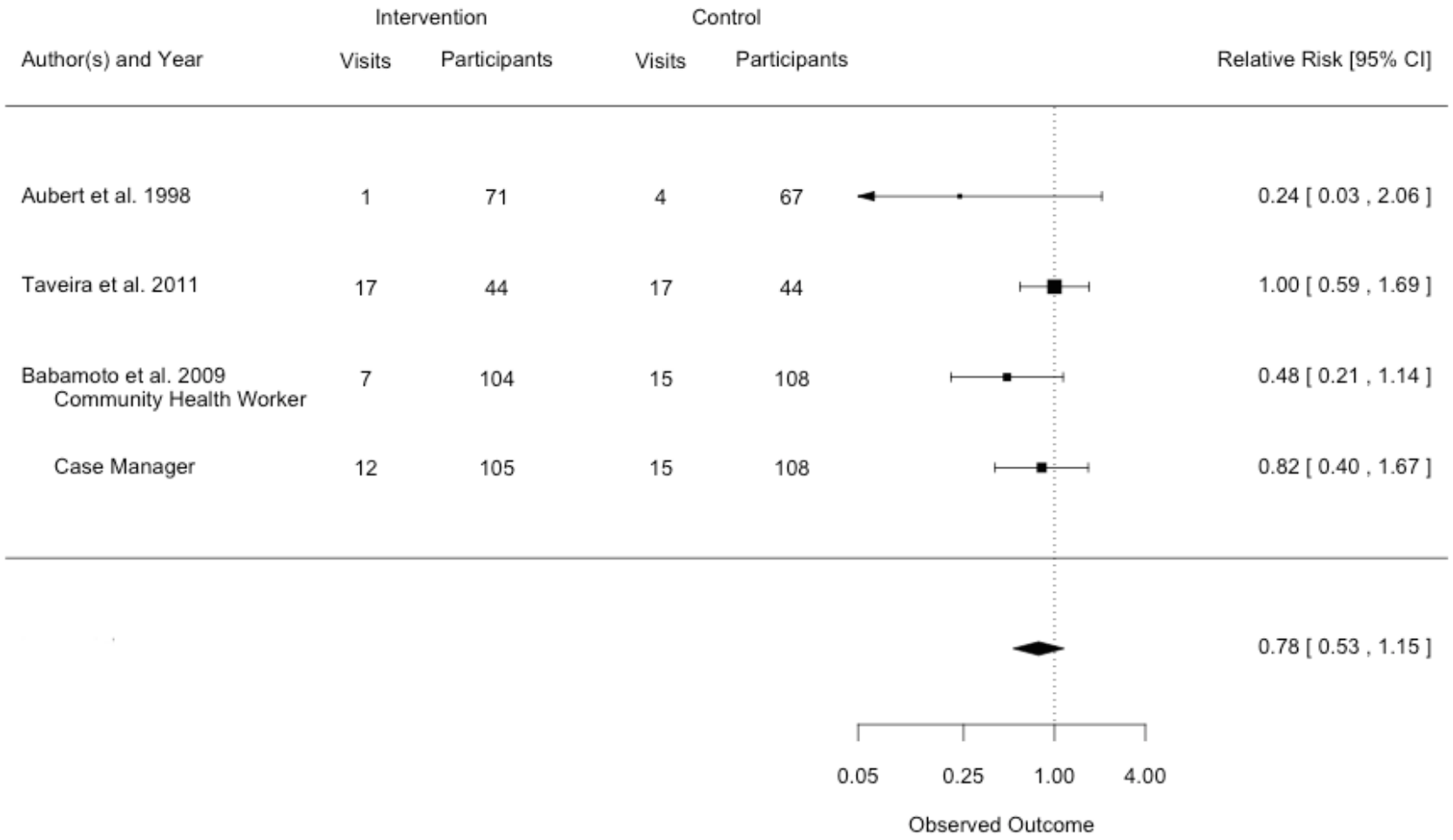
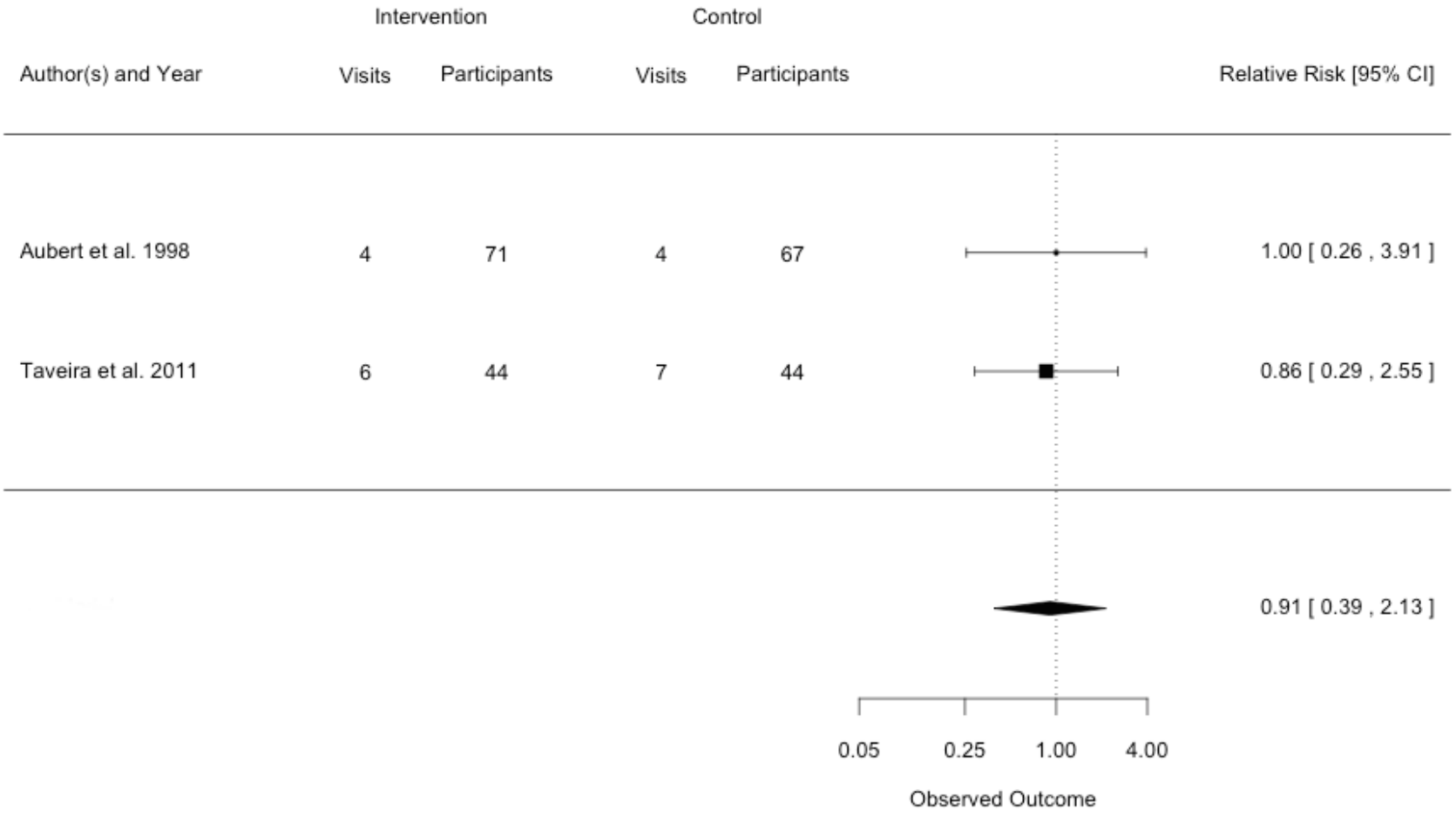


Table 4 - Hospital Utilization

Author, year	Risk of Bias (overall)	Outcome Timing (in months)	Study Arm (N)	End of study hospitalization counts	Association Measure of Hospitalization (95% Confidence Interval) / Type of Association Measure
Wu, 2011	Medium	6	Control (77)	17	
			Intervention (81)	8	0.45 (0.21-0.98) / RR
Aubert, 1998	Medium	12	Control (67)	4	
			Intervention (71)	4	1.00 (0.27-3.75) / RR
Gary, 2009	Low	36	Control (273)	317	
			Intervention (269)	265	0.83 (0.64-1.07) / IRR
Taviera, 2011	Medium	6	Control (44)	7	
			Intervention (44)	6	0.86 (0.32-2.32) / RR

Figure 3 – Hospitalization Meta-analysis



Appendix 1 - Search terms

PubMed
5/13/14 Diabetes Mellitus, Type 2 AND (Preventive Health Services OR Patient Care Management OR Health Education OR Counseling) AND (Emergency Department OR Hospitalization OR "Hospitals/utilization"[Mesh])

CINAHL
5/14/14 (MH "Diabetes Mellitus, Type 2") AND ((MH "Preventive Health Care+") OR "patient care management" OR (MH "Disease Management") OR (MH "Case Management") OR (MH "Health Education+") OR (MH "Patient Education+") OR (MH "Diabetes Education")) AND ((MH "Emergency Service+") OR "emergency room" OR (MH "Hospitalization+"))

Embase
5/14/14
('type 2 diabetes'/exp OR 'type 2 diabetes' OR 'non insulin dependent diabetes mellitus'/exp) AND ('patient care management'/exp OR 'patient care management' OR 'case management'/exp OR 'patient education'/exp OR 'patient education' OR 'diabetes education'/exp OR 'diabetes education' 'preventative health care' OR 'preventative health services') AND ('emergency room'/exp OR 'emergency room' OR 'emergency ward'/exp OR 'emergency ward' OR 'emergency health service'/exp OR 'hospitalization'/exp OR 'hospitalization') AND ([embase]/lim OR [embase classic]/lim)

Appendix 2 – Fulfillment of Disease Management Criteria

CM = Case Manager (Registered Nurse or Pharmacist), CHW = Community Health Worker

Author Name, Year	Education	Coaching	Monitoring	Care Coordination	Treatment Adjustment	Contact frequency	Method of Contact
Wu, 2011	4 weekly education sessions initially	CM called to follow-up 8-16 weeks later				5 contacts over 6 months	In-person + telephone
Aubert, 1998	5 week education program with quarterly follow-up	CM gave guidance for meal planning and exercise.	CM monitored blood glucose for treatment adjustment	CM met bi-weekly with providers	CM adjusted treatment base on algorithm.	1 contact per week for patients with insulin. Contact per 2 weeks for patients with oral hypoglycemic.	In-person + telephone
Gary, 2009	CM provided clinical education	CHW focused on medication adherence, appointment adherence, and socioeconomic issues.	CHW measured random blood glucose and blood pressure.	CM provided written and verbal feedback to patients' providers.		Minimum of 3 times/year for CHW. Minimum 1 time/year for CM.	In-person + telephone
Taveira, 2011	First hour of session is spent on education led by nurse, pharmacist, or nutritionist.		CM monitored blood glucose control using home diary.		CM used home diary and treatment algorithm to adjust treatment.	4 weekly 2-hour sessions, followed by 5 monthly 2-hour sessions	In-person
Borges, 2011	CM provided dietary and pharmacological education.		CM was able to monitor clinical and admission data.		CM adjusted treatment based on algorithm.	Monthly	In-person
Babamoto, 2009	CHW provided 10 week 1-on-1 educational sessions, based on American Diabetes Association standards.	CHW made follow-up calls or visits to help address barriers in self-care.				Average of 11.3 visits over 6 months.	In-person + telephone
	CM provided as-needed education based on American Diabetes Association standards.		CM measured patient clinical outcomes.			Average of 1 visit per month.	In-person + telephone

Appendix 3 –Study Quality Assessment*

Author/ year	Study Arm (N)	Attrition (%)	Ascertainment of Utilization Outcome	Risk of Bias
Gary, 2009	Control (273)	7.3%	Chart review and inquiry at local hospitals	Low
	Intervention (269)	12.6%		
Wu, 2011	Control (77)	5.2%	Self Report	Medium
	Intervention (81)	11.0%		
Aubert, 1998	Control (67)	28.0% Not clear how those lost to follow up were distributed in the two groups.	Uncertain	Medium
	Intervention (71)			
Taviera, 2011	Control (44)	4.5%	Uncertain	Medium
	Intervention (44)	0.0%		
Borges, 2011	Control (31)	0.0%	Claims Data	Medium
	Intervention (40)	17.5%		
Babamoto, 2009	Control (108)	50.0%	Self Report	High
	Community Health Worker (104)	28.0%		
	Case Manager (105)	43.0%		

*This table is to present common problems that were found during this review, I also compared studies based on the other quality metrics described in the methods section (data not published).